

**HL7 SPL Working Group Process Communication Forum Telecon
Wednesday, May 05, 2010**

Check out the SPL Working Group WIKI @:
<http://spl-work-group.wikispaces.com>

Questions on SPL:

ER/DL regulatory questions? Send to edrls@fda.hhs.gov

SPL technical questions? Send to spl@fda.hhs.gov

Meeting Minutes:

FDA Assessment of Outdated SPL on DailyMed

In general, SPL quality is improving, and more SPL are getting to DailyMed. And they are being viewed: 7.5 million hits per month on DailyMed in January 2010.

March 2010: audit of the SPL coming in, in addition to requests/questions from hospitals, other federal agencies. FDA did an assessment of NDAs approved since June 2009, looking at final SPL submitted to the Application vs versions posted on DailyMed.

Over 100 supplemental applications that did not have up-to-date SPL on DailyMed, and had submitted SPL to the Division (via Application Review)

Most recent guidance specifically mentioned sending the SPL to the eList system. Some responses:

- Referenced the approval letter text. Approval letters had had text that specifically mentioned sending the updated SPL to the Review Division (and the Division would forward to NLM)
- We need time to convert to the new process (testing software, etc)
- 'We only need to submit during June or December'

Only 14 days to submit via eList? Some concerns

Concern: If the request is submitted to eList, final SPL does not get submitted to the Review Division. Most recent SPL would not be on the eCTD backbone. Concern is that the final labeling would not be available on the backbone (going forward).

Response: Link on accessdata (FDA web repository) provides an equivalent, and removes the duplicative submission of materials.

Concern: Sponsor may not actually have the impacted labeling (like packaging) in public distribution

Response: If you have label artwork that is still out on the market, and the content of labeling changes, you include the current artwork with the new content of labeling. FDA encourages sponsors to disseminate safety information to the public as quickly as possible.

Concern: Individual package/presentation not available for purchase yet.

Response: You could update the content of labeling and leave out the NDC info within the product element.

Concern: Users may need guidance on how to locate 'current' label. Lots of possible confusion w/ similarly-named labeling (including generics, private label distributors, etc.)

Response: It is the responsibility of the Generic companies to check regularly, to monitor, for updates to RLD (Reference Listed Drug) labeling.

Updated validation rules

<http://spl-work-group.wikispaces.com/Validation+Rules+Modifications+--+2010>

http://spl-work-group.wikispaces.com/file/view/Delta_Validation_Rules-2.xls

- The biggest error with SPL submission right now is that a listing file is submitted before a valid Labeler Code Request is on file.
- The DUNS number for the Labeler must be included in the Drug Listing file – and the numbers must match.

D&B is not comfortable with a release of a comprehensive list of DUNS numbers as connected to Labeler Codes. For now, If you need to know this information for a particular Labeler Code's DUN number, contact SPL@fda.hhs.gov

- SPL Authors are changing their setids between submissions. The only way to get the setid back if the file is not on DailyMed is to contact SPL@fda.hhs.gov and request them to hunt down the previous setid.
- Registrant information should only be completed if you are listing on behalf of the private label distributor.
- If the marketing status is not completed, then there should be one or more establishments.
- Validation procedure: if a product is no longer on the market, and you don't have a principal display panel to include to delist the product, the SPL will fail validation. In this case, contact spl@fda.hhs.gov and ask to have that file removed manually.
- If you submit a listing file, eList will check that the business operation in the listing matches an entry in the previously submitted establishment registration.

- Repacker listing should include the original manufacturer Product code in the Source Code field
- Each company is issued an NDC configuration at the time they receive a Labeler Code. The system assumes that you enter the NDC configuration correctly the first time you enter it into SPL. A future NDC change in configuration (hyphen placement only) would fail validation.
Contact spl@fda.hhs.gov to override an error only in the placement of hyphens (NDC configuration) not the numbers.
- Product Trade Name, Generic Name – should contain no special symbols

Concern: Content of Labeling – please find a way to make the stylesheet rules and content of labeling more clear. And include an explanation of the toolbar functions for Xforms.

Response: Toolbar explanation – good idea! Look for this in the future – either in an e-Book or other form.

Concern: Where can sponsors, other registrants get a list of Business Operations w/ definitions?

Response: Business Operations – if there were a list of these posted with definitions, it would be posted on the eDRLS webpage.

Device subteam

Devices page on RCRIM WIKI:

[http://wiki.hl7.org/index.php?title=Medical_Product_Information_\(SPLr5\)](http://wiki.hl7.org/index.php?title=Medical_Product_Information_(SPLr5))

SPL Device Subteam leader: myron.finseth@medtronic.com

Meetings to be held alternate Thursdays

First meeting scheduled for May 6, 2010; meetings occur every other Thursday, 10:30 ET
Telecom: 770-657-9270 . Passcode: 745896

FYI

Minutes of previous Process Team meetings are here:

<http://spl-work-group.wikispaces.com/Process+Communications+Forum>

FDA is planning for product/type specific training sessions
First sessions are likely to be:

- Cosmetics that are also drugs
- Homeopathic substances